

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT: **ADAMS, William M.**

SERIAL NO: **09/991,381**

FILED: **10/22/2001**

EXAMINER: **KOPPIKAR, VD**

GROUP ART UNIT: **3686**

DOCKET: **T8469833US**

CONF. NO.: 2660

ENTITLED: **ADJUDICATING PHARMACEUTICAL DRUG  
SAMPLE DISTRIBUTION SYSTEM AND METHOD**

**Pre-Appeal Brief Request for Review**

Date: March 10, 2010

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Commissioner:

This communication is filed electronically in response to the Final Office Action dated 01/14/2010. Applicant respectfully requests review of the final rejection in the above-identified application.

No amendments are being filed with this request.

This request is being filed with a Notice of Appeal, including the Notice of Appeal fee of \$270.

The review is requested for the reasons stated on the attached sheets totalling no more than 5 pages.

## **ARGUMENT**

The Examiner rejected claims 1-2, 4-7, 9-14, 15-20, 22, 24-27, 29-32, 34, and 36-38 under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,832,449 to Cunningham in view of US Patent Number 5,945,651 to Chorosinski and in even further view of US Patent Number 5,098,131 to Tucker.

Claim 1 currently recites: *A computer implemented method for tracking distribution of pharmaceutical drug samples prescribed by a prescriber to a pre-identified patient, comprising a step of adjudicating by a computer, at a health plan adjudication database system, a claim associated with the pre-identified patient for the use of a token representative of a pharmaceutical drug sample, wherein the token is provided by the prescriber to the pre-identified patient for obtaining the pharmaceutical drug sample from a drug dispenser, and wherein the token displays token processing information, the token processing information at least including contact information for adjudication assistance.*

**A.** The Examiner acknowledges that Cunningham does not disclose "...a pre-identified patient...", but then asserts that the Office takes the position that this feature is well-known in the health care and pharmaceutical dispensing industry, as found in Chorosinski. The Examiner's stated rationale for the combination is that one of ordinary skill in the art would make this modification to Cunningham to ensure that prescription fraud does not take place and also to ensure that the prescription sample is dispensed only to the correct, identified patient since prescriptions can be dangerous if taken without approval from an authorized prescriber.

However, Cunningham already incorporates stringent safeguards to ensure correct dispensation of the drug sample to the correct person, as described at columns 10 and 11 respectively of Cunningham:

40 However, before the pharmacy can fill the prescriptive  
trial product of any presented product trial media **18**, the  
product trial media must be subjected to a “validation”  
procedure. The “validation” procedure is basically illus-  
45 trated in FIGS. 7A–7B. Essentially, this validation proce-  
dure establishes that the presented product trial media **18** is  
authentic, still within an acceptable date range, has been  
activated by a prescriber, and has not previously been  
validated. Once validation is established for any presented  
product trial media, then the participating pharmacy can  
50 issue the prescriptive trial pharmaceutical product to the  
patient.

product trial media **18**. In addition, both the pharmacy and  
the patient sign the now validated product trial media **18**.  
Once validation is established the pharmacy then dispenses  
pharmaceutical trial product authorized by that valid product  
trial media and permanently stores the validated media. At  
the same time, the central computing station **12** records the  
full validation data within its database by showing that a  
25 particular product trial media **18** has been validated, the date  
of such validation, and the identity of the pharmacy vali-  
dating the same.

Applicant respectfully submits that the patient signing the validated product  
trial media of Cunningham, after authentication by the pharmacy, is sufficient to  
prevent any prescription fraud taking place, and also to ensure dispensation to the  
correct patient. So Cunningham already discloses stringent measures and  
safeguards in place to prevent prescription fraud and ensure correct dispensation of  
the drug sample, and there would be no advantage gained, and thus no reason or  
motivation for one skilled in the art, to combine Cunningham with Chorosinski, with  
regard to a patient pre-identification feature.

Applicant respectfully submits that the Examiner’s proposed combination of  
Cunningham with Chorosinski, therefore, is based on an inappropriate hindsight  
analysis of claim 1.

**B.** The Examiner acknowledges that neither Cunningham nor Chorosinski teach  
or suggest the feature of “...wherein the token displays token processing  
information, the token processing information at least including contact information  
for adjudication assistance....”, and proposes that this feature is taught by Tucker.

However, the Examiner then admits that Tucker does not disclose that the information included in the token is contact information for adjudication assistance, but asserts that the Office takes the position that this feature is inherent from the disclosure of Tucker, since “the customer’s use of the token necessarily involves that the retailer be given contact information so that they can at least begin the process of reimbursement (adjudication) for allowing the consumer to use the token”.

Firstly, the Examiner has not applied the correct standard of law with regard to inherency of the above feature of Tucker, in rejecting claim 1 based on obviousness. The Examiner may not properly reject a claim under section 103(a) unless all the elements of the claim are disclosed. The Supreme Court reaffirmed in *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 2007 WL 1237837, that the need to demonstrate the presence of all claim limitations in the prior art, when the legal theory is based upon obviousness due to a combination of prior art references, has not been obviated. In the event that the cited prior art references fail to disclose or suggest all of the elements recited in the claim, then combining elements from the references would not yield the claimed subject matter, regardless of the extent of any teaching, suggestion or motivation.

Thus, none of the cited references of Cunningham, Chorosinski or Tucker teach or suggest the feature of “....wherein the token displays token processing information, the token processing information at least including contact information for adjudication assistance....”.

Secondly, it is apparent that the Examiner has minimized the purposes and benefits of displaying the adjudication assistance information as serving to accomplish merely a benefit of reimbursement of the retailer. Instead, a review of paragraph [0045] and [0047] of Applicant’s published application establishes a better context and a wider scope of purposes for displaying such information on the token.

For the above reasons, none of the cited references of Cunningham, Chorosinski, and Tucker, either alone, or in combination, discloses the Applicant's invention as presently claimed in claim 1.

Claims 3, 23, 28 and 35 were rejected under 35 USC 103(a) as being unpatentable over Cunningham in view of Chorosinski in view of Tucker as applied to claims 2, 22, 27, 34 respectively, and further in view of US Patent Number 5,666,490 to Gillings.

Claims 8, 21 and 33 were rejected under 35 USC 103(a) as being unpatentable over Cunningham in view of Chorosinski in view of Tucker, as applied to claims 1, 15, 27 respectively and further in view of US Patent Number 6,564,121 to Wallace.

Accordingly, Applicant submits that claim 1 is not obvious in view of the cited references. Further, Applicant relies on the above arguments in response to the Examiner's rejection of claims 2 to 38 under 35 U.S.C. 103(a) in that the claimed features of claim 1 are similarly included in claims 2 to 38.

Thus, Applicant respectfully submits that the final rejection of all claims based on the cited references is improper and should be reversed.

For all the reasons set out above, Applicant respectfully submits that claims 1-38 are in condition for allowance and action toward that goal is respectfully requested.

Respectfully submitted,

          /Henry Ohab/          

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